K092953

5.0 510(k) Summary

As required by 21 CFR Section 807.92(c).

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (408) 400-8230 Fax number: (408) 541-6439
Contact:	Russel K. Enns, Ph.D.
Date of Preparation:	September 23, 2009
Device:	
Trade name:	Xpert® *vanA*
Common names:	Xpert® *vanA* Assay
Type of Test:	Qualitative nucleic acid amplification test of the *vanA* gene directly from rectal swabs.
Classification:	II
Classification name:	System, test, genotypic detection, resistant marker, *Enterococcus* species
Regulation number:	866.1640
Procode:	NIJ
Classification Advisory Committee:	Microbiology
Panel:	83
Predicate Devices:	BD IDI-Van*R*® Assay [510(k) #K061686] Remel Esculin Azide Agar w/6 µg/mL vancomycin [510(k) #K972359]

DEC 17 2009

Device Description:

The Cepheid Xpert *vanA* Assay is a rapid, automated *in vitro* diagnostic test for qualitative detection of the *vanA* gene sequence associated with vancomycin resistance in bacteria obtained directly from rectal swab specimens. The Xpert *vanA* Assay system performs real-time multiplex polymerase chain reaction (PCR) for detection of DNA after an initial sample processing step. The assay is performed on the Cepheid GeneXpert® Dx System.

The specimen is collected on a double swab, one of which is placed in a tube containing elution reagent. Following brief vortexing, the eluted material and two single-use reagents (Reagent 1 and Reagent 2) that are provided with the assay are transferred to

different, uniquely-labeled chambers of the disposable fluidic cartridge (the Xpert *vanA* cartridge). The user initiates a test from the system user interface and places the cartridge into the GeneXpert® Dx System instrument platform, which performs hands-off real-time, multiplex polymerase chain reaction (PCR) for detection of DNA. In this platform, additional sample preparation, amplification, and real-time detection are all fully-automated and completely integrated.

The GeneXpert® System consists of a GeneXpert instrument, personal computer, and the multi-chambered fluidic cartridges that are designed to complete sample preparation and real-time PCR for detection of the *vanA* gene that is associated with vancomycin-resistant enterococci (VRE) in less than 45 minutes. Each instrument system has 1 to 16 randomly accessible modules that are each capable of performing separate sample preparation and real-time PCR tests. Each module contains a syringe drive for dispensing fluids, an ultrasonic horn for lysing cells or spores, and a proprietary I-CORE® thermocycler for performing real-time PCR and detection.

The Xpert *vanA* Assay includes reagents for the detection of the *vanA* resistant gene as well as an internal sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor the presence of inhibitor(s) in the PCR assay. The SPC also ensures the PCR conditions (temperature and time) are appropriate for the amplification reaction and that the PCR reagents are functional. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

Device Intended Use:

The Cepheid Xpert® *vanA* Assay performed in the GeneXpert® Dx System is a qualitative *in vitro* diagnostic test designed for rapid detection of the *vanA* gene sequence associated with vancomycin resistance in bacteria obtained from rectal swab specimens from patients at risk for intestinal colonization with vancomycin-resistant bacteria. The test utilizes automated real-time polymerase chain reaction (PCR) to detect the *vanA* gene that is frequently associated with vancomycin-resistant enterococci (VRE). The Xpert *vanA* Assay is intended to aid in the recognition, prevention, and control of vancomycin-resistant organisms that colonize patients in healthcare settings. The Xpert *vanA* Assay is not intended to diagnose infections caused by vancomycin-resistant bacteria nor to guide or monitor treatment for vancomycin-resistant bacterial infections. Concomitant cultures are necessary to recover organisms for identification of vancomycin-resistant bacteria, antimicrobial susceptibility testing and for epidemiological typing.

Substantial Equivalence:

The Xpert *vanA* Assay is substantially equivalent to the BD IDI-Van*R* Assay (510(k) #K061686). Both assays detect vancomycin resistance genes directly from rectal swab specimens from patients at risk for VRE colonization. Both assays use real-time PCR amplification and fluorogenic target-specific hybridization detection.

Table 5.1 shows the similarities and differences between the Xpert *vanA* Assay and the BD IDI-Van*R* Assay.

The Xpert *vanA* is also substantially equivalent to the reference direct culture method. The reference culture method is the Remel Bile Esculin Azide agar with 6 μg/mL vancomycin (BEAV) [510(k) #K972359].

Performance characteristics of the Xpert *vanA* Assay were determined in a multi-site prospective investigation study at three US institutions by comparing the Xpert *vanA* Assay to reference culture followed by bi-directional sequencing confirmation on those samples positive for *vanA* by culture.

Table 5.2 compares the new device with the reference direct culture method. The test results showed the Xpert *vanA* Assay to be substantially equivalent to the current standard of care, the reference culture method.

Table 5.1: Similarities and Differences between the Xpert *vanA* Assay and the IDI-VanR Assay

Similarities		
	Device	**Predicate**
Item	**Xpert *vanA* Assay**	**IDI-VanR Assay (K061686)**
Intended Use	The Cepheid Xpert® *vanA* Assay performed in the GeneXpert® Dx System is a qualitative in vitro diagnostic test designed for rapid detection of the *vanA* gene sequence associated with vancomycin resistance in bacteria obtained from rectal swab specimens from patients at risk for intestinal colonization with vancomycin-resistant bacteria. The test utilizes automated real-time polymerase chain reaction (PCR) to detect the *vanA* gene that is frequently associated with vancomycin-resistant enterococci (VRE). The Xpert *vanA* Assay is intended to aid in the recognition, prevention, and control of vancomycin-resistant organisms that colonize patients in healthcare settings. The Xpert *vanA* Assay is not intended to diagnose infections caused by vancomycin-resistant bacteria nor to guide or monitor treatment for vancomycin-resistant bacterial infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for further confirmatory identification of vancomycin-resistant bacteria.	The IDI-VanR® Assay is a qualitative in vitro test for the rapid detection of vancomycin-resistance enterococci (VRE). The assay is performed on an automated real-time PCR instrument with rectal swabs from patients at risk for VRE colonization. The IDI-VanR® Assay can be used as an aid to identify, prevent and control vancomycin-resistant colonization in healthcare settings. Concomitant cultures are necessary to recover organisms for epidemiological typing, susceptibility testing and for further confirmatory identification. The IDI-VanR® Assay is not intended to diagnose VRE infections nor to guide or monitor treatment for VRE infections.
Type of test	Qualitative	Same

Similarities		
Technological Principles	Fully-automated nucleic acid amplification (DNA); real-time PCR	Same
Specimen Type	Direct from rectal Swabs	Same
Test Cartridge	Disposable single-use, multi-chambered fluidic cartridge.	Disposable single-use PCR tube
Probes	TaqMan® Probes	Molecular Beacons
Controls	Internal sample processing control (SPC) and probe check control (PCC). External controls available.	One internal reagent control and external positive and negative controls required per run
DNA Target Sequence	Detects gene sequences for the *vanA* encoded resistance to vancomycin/ teicoplanin.	Detects gene sequences for VanR (*vanA* and *vanB*) encoded resistance to vancomycin/teicoplanin.
Rapid test results	Less than 45 minutes to results.	Approximately 120 minutes.
Interpretation of test results	Diagnostic software of the Cepheid GeneXpert Dx System	Diagnostic software of the Cepheid SmartCycler Dx System
Differences		
	Device	**Predicate**
Item	**Xpert *vanA* Assay**	**IDI-VanR Assay (K061686)**
Instrument System	Cepheid GeneXpert Dx System	Cepheid SmartCycler
DNA Target Sequence	Detects sequences for the *vanA* gene.	Detects sequences for vancomycin resistance [*vanR* (*vanA* and *vanB)]* gene, but does not differentiate *vanA* from *vanB*.
Sample Extraction /Fluidics	Self-contained and automated after swab elution and two single-dose reagent additions.	Manual
Users	Operators with no clinical lab experience to experienced clinical laboratory technologists.	CLIA High Complexity Laboratory Users

Table 5.2: Similarities and Differences between the Xpert *vanA* Assay and the Reference Culture Method Predicate Device

Similarities		
	Device	**Culture Method Predicate**
Item	**Xpert *vanA* Assay**	**Remel Bile Esculin Azide agar with 6 µg/mL vancomycin (BEAV) [510(k) #K972359]**
Intended Use	The Cepheid Xpert® *vanA* Assay performed in the GeneXpert® Dx System is a qualitative *in vitro* diagnostic test designed for rapid detection of the *vanA* gene sequence associated with vancomycin resistance in bacteria obtained from rectal swab specimens from patients at risk for intestinal colonization with vancomycin-resistant bacteria. The test utilizes automated real-time polymerase chain reaction (PCR) to detect the *vanA* gene that is frequently associated with vancomycin-resistant enterococci (VRE). The Xpert *vanA* Assay is intended to aid in the recognition, prevention, and control of vancomycin-resistant organisms that colonize patients in healthcare settings. The Xpert *vanA* Assay is not intended to diagnose infections caused by vancomycin-resistant bacteria nor to guide or monitor treatment for vancomycin-resistant bacterial infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for further confirmatory identification of vancomycin-resistant bacteria.	Remel Bile Esculin Azide agar with 6 µg/mL vancomycin is a plated medium recommended for use in qualitative procedures as a selective and differential medium for the primary isolation of vancomycin resistant enterococci from surveillance cultures. This product is not intended for use as a method of antimicrobial susceptibility testing. Confirmation of vancomycin resistance by an approved method is recommended as some organisms on initial isolation may overcome the inhibitory effects of the medium.
Single use	Yes	Same
Type of test	Qualitative	Same
Specimen Type	Direct from rectal swabs	Direct from rectal swab or stool.

Differences		
	Device	**Culture Method Predicate**
Item	**Xpert *vanA* Assay**	**Remel Bile Esculin Azide agar with 6 µg/mL vancomycin (BEAV) [510(k) #K972359]**
Technology	Fully-automated nucleic acid (DNA) preparation and amplification; real-time PCR. Detect sequences specific to *vanA* gene	Phenotypic detection of vancomycin-resistant enterococci (VRE) based on culture growth
Mode of Detection	Presence of *vanA* gene	Growth or no growth on 6mg/mL vancomycin agar
Specimen Type	Direct from rectal swabs	Culture grown direct from rectal swab or stool
Internal Controls	Sample processing control (SPC) and probe check control (PCC).	Not applicable
Interpretation of test results	Diagnostic software of the GeneXpert Dx System	Visual interpretation

Non-Clinical Studies:

Analytical Reactivity (Inclusivity)

Thirty vancomycin-resistant enterococci strains and 20 vancomycin sensitive enterococci strains, provided by the CDC, were tested using the Xpert *vanA* Assay. Of the 30 vancomycin-resistant enterococci strains, 10 were identified as *vanA* positive. Enterococci strains were selected to broadly represent the genetic diversity found in enterococci. Stock cultures were prepared by suspending the bacterial growth from agar plates in PBS buffer containing 15% glycerol. The concentration of each stock was adjusted to $5.6x10^9$ to $2.1x10^{10}$ CFU/mL. All strains were serially diluted to approximately 360 CFU/swab and tested in triplicate.

Under the conditions of this study, all 20 vancomycin sensitive strains were reported as "vanA NEGATIVE," as expected. Among the 10 *vanA* positive vancomycin-resistant enterococci strains tested, one strain was reported as "vanA NEGATIVE." When this strain was sequenced the data matched 100% to a reference *vanB* sequence, confirming that the Xpert *vanA* Assay accurately reported the strain "vanA NEGATIVE." The remaining 9 *vanA* positive vancomycin resistant enterococci strains were correctly reported as "vanA POSITIVE," as expected. Among the 20 non-*vanA* vancomycin resistant enterococci strains, all were reported as "vanA NEGATIVE," as expected.

Analytical Sensitivity

Studies were performed to determine the 95% confidence intervals for the analytical limit of detection (LoD) of *Enterococcus faecium* (*vanA*) diluted into a fecal matrix of human origin that can be detected by the Xpert *vanA* Assay. The fecal matrix consisted of autoclaved human liquid feces (*vanA* negative) diluted 1:10 in Tris buffer. The LoD is defined as the lowest number of colony forming units (CFU) per swab that can be reproducibly distinguished from negative samples with 95% confidence.

The analytical LoD was estimated using 4 to 10 replicates at each dilution. The LoD was confirmed by running a total of 20 replicates at the estimated LoD concentration. Under the conditions of this study, the limit of detection for the Xpert *vanA* Assay on a simulated rectal swab specimen is 37 CFU.

Linearity

A study was conducted to define the reportable range of the Xpert *vanA* Assay and demonstrate a linear between target input and assay output. Linearity was evaluated using *Enterococcus faecium* (*vanA*) cells serially diluted over 6 logs and processed using the Xpert *vanA* Assay. The diluted cells resulted in a cell concentration dose range of 50 CFU/test to $5x10^7$ CFU/test. Replicates of four (4) were tested at each concentration.

For *enterococci* cells, under the conditions of this study, the Xpert *vanA* Assay responds linearly ($r^2 = 0.994$) with respect to *vanA* detection as a function of *Enterococcus faecium* cell input over 6 logs (50 – $5x10^7$ CFU/test). The reportable Ct range is 12.1 to 35.3 (cut-off Ct = 40.0). PCR efficiency for the *vanA* reaction is 87.7 %.

Analytical Specificity

Forty-two bacterial and fungal strains were collected, quantitated and tested using the Xpert *vanA* Assay. The strains originated from the American Type Culture Collection (ATCC), Culture Collection University of Göteborg (CCUG), German Collection of Microorganisms and Cell Cultures (DSMZ), and the Centers for Disease Control and Prevention (CDC).

The organisms tested were identified as Gram-positive (22), Gram-negative (18), including antibiotic-resistant strains of *Pseudomonas spp.* and *Acinetobacter spp.*, and yeast (2). The organisms were further classified as aerobic (24), anaerobic (14) or microaerophillic (2). Of the species tested, 2 vancomycin-sensitive strains of *E. faecalis* and *E. faecium* were included.

Each strain was tested in triplicate at concentrations ranging from $8.5x10^8$ to $2.3x10^{10}$ CFU/swab. Positive and negative controls were included in the study. Under the conditions of the study, all isolates were reported "vanA NEGATIVE". The analytical specificity was 100%.

Interfering Substances

Sixteen exogenous substances occasionally used or found in stool were tested for interference with the Xpert *vanA* Assay. The substances tested are listed in Table 5.3. None of the 16 substances tested showed detectable interference for *vanA*. However, Hydrocortisone cream (1 % Hydrocortisone) and Pepto-Bismol® (1 - 5% Bismuth subsalicylate) may slightly interfere with the Xpert *vanA* Assay. When tested in the Interference study, Hydrocortisone cream and Pepto-Bismol® resulted in slightly higher Ct values relative to the buffer control.

Table 5.3: Substances Tested and Showing No Assay Interference for *vanA*

Substance	**Substance**
Whole Blood Karolinska University Hospital	Vaseline Unilever
Mucin (porcine) Sigma	Dulcolax® Boehringer Ingelheim Pharmaceuticals
Kaopectate® Chattem	Preparation H® Portable Wipes Wyeth Consumer Healthcare
Imodium® McNeil-PPC	Vancomycin Fluka
Fleet® CB Fleet Company	Metronidazole Actavis
Fecal fats Karolinska University Hospital	Anusol® Plus TM Warner-Lambert Company
K-Y Jelly/Gelée® McNeil-PPC	E-Z-HD™ High Density Barium Sulfate for suspension E-Z-EM Canada
[A]Hydrocortisone Cream Longs Drugs	[A]Pepto-Bismol® Proctor & Gamble

[A]When tested in the Interference study, results showed slightly higher Ct values relative to the buffer control

Clinical Studies

Clinical Comparison Study

Performance characteristics of the Xpert *vanA* Assay were determined in a multi-site prospective investigation study at three US institutions by comparing the Xpert *vanA* Assay to reference culture followed by bi-directional sequencing for confirmation on vancomycin-resistant *E. faecalis* or *E. faecium* isolates.

Subjects included individuals whose routine care called for VRE testing. One swab from a double swab set was used for patient management; the other swab was used for the Xpert *vanA* Assay testing. The leftover swab designated for patient management was sent to a central laboratory for reference culture.

Leftover specimen swabs designated for culture testing were stored at 2-8°C and shipped on ice packs to the central culture laboratory within 48 hours of collection. Reference culture was initiated within 16 hours of receipt or within 5 days of swab collection.

Each swab was subsequently placed into bile esculin azide broth with 8 µg/ml vancomycin. The plates were incubated at 35°C and examined at 48 and 72 hours. The broth was also incubated at 35°C for 48 hours and subcultured to a bile esculin azide agar with 6 µg/ml of vancomycin.

Small, gray colonies with a black halo were considered suspicious for VRE. Presumptive identification was accomplished by performing a Gram stain, catalase and disc pyr (L-pyrrolidonyl-beta-naphthylamide) test. Presumptive VRE specimens were Gram-positive *cocci* or *coccobacilli* and pyr positive. Presumptive VRE was definitively identified using the API20S strip (BioMérieux, France). Finally, VRE isolates were tested for their susceptibility to glycopeptides using vancomycin ε-test strips (AB Biodisk, Sweden). Susceptibility to teicoplanin for the isolates was determined by agar dilution. Following reference culture testing, DNA was prepared from vancomycin-resistant *E. faecilis* or *E. faecium* isolates, and sent to a second reference laboratory for bi-directional sequencing using alternative *vanA* specific primers (*i.e.*, different from those used in the Xpert *vanA* Assay).

Performance of the Xpert *vanA* Assay was calculated relative to the results of direct culture with bi-directional sequencing, and enriched culture with bi-directional sequencing.

Overall Results

A total of 1231 specimens were tested by Xpert *vanA* Assay, culture and bi-directional sequencing.

Performance vs. Direct Culture

Relative to direct culture with bi-directional sequencing, the Xpert *vanA* Assay demonstrated a percent positive agreement of 98.4% and a percent negative agreement of 92.4% (Table 5.4).

Table 5.4: Xpert *vanA* Assay Performance vs. Direct Culture with Bi-directional Sequencing

		Direct Culture + Sequencing		
Xpert *vanA* Assay		Pos	Neg	Total
	Pos	126	84	210
	Neg	2	1019	1021
	Total	128)	1103	1231
	% Positive Agreement:	98.4%		
	% Negative Agreement:	92.4%		
	Accuracy:	93.0%		
	PPV:	60.0%		
	NPV:	99.8%		
	Prevalence:	10.4%		

Of the Xpert *vanA* Assays run on eligible specimens, 94.0% (1180/1255) of these specimens were successful on the first attempt. The remaining 75 gave indeterminate results on the first attempt (26 "INVALID", 49 "ERROR" and 0 "NO RESULT"). Sixty two (62) of the75 indeterminates on the first attempt had sufficient sample for retest, 82.3% (51/62) gave a result on the second the attempt. Overall assay success rate (combining the first and second attempts) was 98.1% (1231/1255).

Performance vs. Enriched Culture

Relative to enriched culture with bi-directional sequencing, the Xpert *vanA* Assay demonstrated a percent positive agreement of 86.5% and a percent negative agreement of 93.5% (Table 5.5).

Table 5.5: Xpert *vanA* Assay Performance vs. Enriched Culture with Bi-directional Sequencing

		Enriched Culture + Sequencing		
		Pos	Neg	Total
Xpert *vanA* Assay	Pos	141 (137)	69 (69)	210 (206)
	Neg	22 (21)	999 (953)	1021 (974)
	Total	163 (158)	1068 (1022)	1231 (1180)

% Positive Agreement:	86.5%
% Negative Agreement:	93.5%
Accuracy:	92.6%
PPV:	67.1%
NPV:	97.8%
Prevalence:	13.2%

Of the Xpert *vanA* Assays run on eligible specimens, 94.0% (1180/1255) of these specimens were successful on the first attempt. The remaining 75 gave indeterminate results on the first attempt (26 "INVALID", 49 "ERROR" and 0 "NO RESULT"). Sixty two (62) of the75 indeterminates on the first attempt had sufficient sample for retest, 82.3% (51/62) gave a result on the second the attempt. Overall assay success rate (combining the first and second attempts) was 98.1% (1231/1255)

Antibiotic Usage

Among the 1231 cases included in the main dataset, antibiotic use within the 3 weeks prior to sample collection was reported for 414 and no antibiotic use was confirmed for 483; for 334 cases, antibiotic status was unknown. Antibiotic use did not cause a statistically significant difference in assay performance.

Reproducibility

A panel of four specimens with varying concentrations of *vanA* was tested on 10 different days by two different operators at each of the three sites (4 specimens x 2 operators/ day x 10 days x 3 sites). One lot of Xpert *vanA* Assay was used at each of the 3 testing sites. Xpert *vanA* Assays were performed according to the Xpert *vanA* Assay procedure. Results are summarized in Tables 5.6.

Table 5.6: Summary of Reproducibility Results (all)[a]

	% Agreement[a]			
Specimen ID	Site 1	Site 2	Site 3	% Total Agreement by Sample
Neg	100% (20/20)	90% (18/20)	100% (20/20)	96.7% (58/60)
vanA High Neg	100% (20/20)	100% (20/20)	95% (19/20)	98.3% (59/60)
vanA Low Pos	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
vanA Moderate Pos	100% (20/20)	95% (19/20)	100% (20/20)	98.3% (59/60)
% Total Agreement by Site	100% (80/80)	96.3% (77/80)	98.8% (79/80)	98.3% (236/240)

[a]For negative and high negative samples, %Agreement = (# negative results/total samples run); for low and moderate positive samples, %Agreement = (# positive results/total samples run).

Conclusions

The results of the nonclinical analytical and clinical performance studies summarized above demonstrate that the Xpert *vanA* Assay is as safe, as effective, and performs as well as the current standard of care, the reference culture method with confirmation of all results by bi-directional sequence analysis. Therefore, the Xpert *vanA* Assay is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC 17 2009

Cepheid®
c/o Russel K. Enns, Ph.D.
Senior Vice President
Regulatory, Clinical & Government Affairs
& Quality Systems
904 Carribean Drive
Sunnyvale, CA 94089

Re: k092953
Trade/Device Name: Xpert® *vanA* Assay
Regulation Number: 21 CFR §866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: NIJ, OOI
Dated: September 23, 2009
Received: September 24, 2009

Dear Dr. Enns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

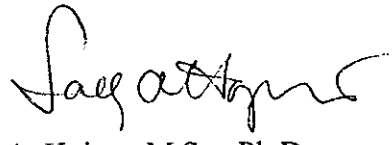
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Cepheid.

4.0 Indications for Use Statement

510(k) Number (if known): k092953

Device Name: Xpert *vanA*

Indications for Use:

The Cepheid Xpert® *vanA* Assay performed in the GeneXpert® Dx System is a qualitative *in vitro* diagnostic test designed for rapid detection of the *vanA* gene sequence associated with vancomycin resistance in bacteria obtained from rectal swab specimens from patients at risk for intestinal colonization with vancomycin-resistant bacteria. The test utilizes automated real-time polymerase chain reaction (PCR) to detect the *vanA* gene that is frequently associated with vancomycin-resistant enterococci (VRE). The Xpert *vanA* Assay is intended to aid in the recognition, prevention, and control of vancomycin-resistant organisms that colonize patients in healthcare settings. The Xpert *vanA* Assay is not intended to diagnose infections caused by vancomycin-resistant bacteria nor to guide or monitor treatment for vancomycin-resistant bacterial infections. Concomitant cultures are necessary to recover organisms for identification of vancomycin-resistant bacteria, antimicrobial susceptibility testing and for epidemiological typing

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Freddie K. Cook

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092953